510(k) SUMMARY

APR 2 9 2013

Singe Use Repositionable Clip, HX-Y0003-U,HX-Y0003-L

April 16, 2013

1 General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No: 8010047
■ Official Correspondent:	Sheri L. Musgnung Regulatory Affairs & Quality Assurance Olympus America Inc. 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610, USA Phone: 484-896-3147FAX: 484-896-7128 Email: sheri.musgnung@olympus.com
■ Manufacturer:	Aomori Olympus Co., Ltd. 248-1 Okkonoki 2-chome Kuroishi-shi, Aomori, Japan 036-0367 Establishment Registration No.: 9614641

2 Device Identification

■ Device Name	HX-Y0003-L HX-Y0003-U
■ Device Trade Name:	Single Use Repositionable Clip
■ Common Name:	Endoscopic clipping device
■ Regulation Number:	21CFR 876.4400
■ Regulation Name:	Hemorrhoidal ligator
■ Regulatory Class:	II
■ Product Code:	FHN (ligator, hemorrhoidal) MND (ligator, esophageal)
■ Classification Panel:	Gastroenterology and Urology

3 Predicate Device Information

- Device Name: Endoscopic Clipping Device HX-5LR-1, HX-6UR-1
  Standard Clip HX-600-135
- Common Name: Endoscopic Clipping Device
- Manufacturer: Olympus Optical Co., Ltd.
- 510(k) No. K013066

4 Device Description

This instrument is intended to be used with Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract. It is indicated to be used for

(1) endoscopic marking

(2) hemostasis for

(a) mucosal/sub-mucosal defects < 3 cm,

(b) bleeding ulcers,

(c) arteries < 2 mm,

(d) polyps < 1.5 cm in diameter,

(e) diverticula in the colon,

(3) anchoring to affix jejunal feeding tubes to the wall of the small bowel,

(4) as a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

The subject device is composed of two parts, the clip and the clip fixing device. The clip can be closed and re-opened. The clip is pre-loaded in the clip fixing device, connected with an operation wire. The clip will open when the slider of the clip fixing device is pushed, and close when it is pulled towards the operator. The clip could be closed and re-opened up to five times. When the slider is pulled further, the clip closes completely. The clip will be released when the slider is pushed.

5 Indications for Use

This instrument is intended to be used with Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract. It is indicated to be used for

(1) endoscopic marking

(2) hemostasis for

(a) mucosal/sub-mucosal defects < 3 cm,

(b) bleeding ulcers,

(c) arteries < 2 mm,

(d) polyps < 1.5 cm in diameter,

(e) diverticula in the colon,

(3) anchoring to affix jejunal feeding tubes to the wall of the small bowel,

(4) as a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

6 Comparison of Technological Characteristics

The proposed subject device HX-Y0003-L and HX-Y0003-U have similar technological characteristics as the predicate device.

Item	Subject device		Predicate device		
Model Name	HX-Y0003-L	HX-Y0003-U	HX-5LR-1	HX-5UR-1	HX-600-135
Trade Name	Single use Repositionable Clip	Single use Repositionable Clip	Endoscopic clipping device	Endoscopic clipping device	Standard Clip
Indications for use	This instrument is intended to be used with Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract. It is indicated to be used for (1) endoscopic marking (2) hemostasis for (a) mucosal/sub-mucosal defects < 3 cm, (b) bleeding ulcers, (c) arteries < 2 mm, (d) polyps < 1.5 cm in diameter, (e) diverticula in the colon, (3) anchoring to affix jejunal feeding tubes to the wall of the small bowel, (4) as a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.		Olympus Rotatable Clip Fixing Device have been designed to be used with Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of (1) endoscopic marking (2) hemostasis for (a) mucosal/sub-mucosal defects<3cm, (b) bleeding ulcers, (c) arteries<2mm, (d) polyps<1.5cm in diameter, (e) divertricula in the colon, (3) anchoring to affix jejunal feeding tubes to the wall of the small bowel, (4) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively.		
Sterilization	Ethylene oxide gas sterilized, disposable		Non sterilized, reusable		Ethylene oxide gas sterilized, disposable
Composition	Clip and a clip fixing device		Clip and a clip fixing device		
Preloaded ready for use	Yes		No		
Tentative clipping	Available		Not available		
Material composition	Clip: Elgiloy and 6Al-4V Titanium Clip Fixing Device: Stainless Steel; HDPE		Clip: Stainless steel and silicone Clip Fixing Device: Stainless Steel		
MRI	MRI conditional		No mention of MRI safety and compatibility		

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Performance testing were conducted including the basic performance, ability of the clip to reopen, the opening width, the rotation mechanism, compatibility with endoscopes, and tensile strength. In addition, bench testing was performed to demonstrate that the clip remains locked under simulated conditions within a two-week duration time period.

Biocompatibility testing was performed on the clip and the delivery device separtely, which demonstrated the devices to be biocompatible.

MRI testing was conducted in accordance with various applicable ASTM standards, which demonstrated the device to be MRI conditional.

The following standards have been applied to the HX-Y0003-L and HX-Y0003-U, Single Use Repositionable Clip:

- ISO 14971
- ANSI/AAMI/ISO 11135-1
- ISO 10993-1
- ISO 10993-3
- ISO 10993-5
- ISO 10993-6
- ISO 10993-10
- ISO 10993-11
- ASTM F1980-7
- ASTM F2052-06e01
- ASTM F2213-06
- ASTM F2182-11a
- ASTM F2119-07
- ASTM F2503-08

7 Conclusion

Based on results of the bench testing performance in comparison to the predicate device, the changes did not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

OLYMPUS MEDICAL SYSTEMS CORP.
% Sheri L. Musgnung
Associate Manager, Regulatory Affairs
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
Center Valley, PA 18034-0610

Re: K123601
Trade/Device Name: Single Use Repositionable Clip, HX-Y0003-L and HX-Y0003-U
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): March 25, 2013
Received (Date on orig SE ltr): March 26, 2013

Dear Sheri L. Musgnung,

This letter corrects our substantially equivalent letter of April 29, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: K123601

Single Use Repositionable Clip,HX-Y0003-L and HX-Y0003-U

Indications For Use:

This instrument is intended to be used with Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract. It is indicated to be used for
(1) endoscopic marking
(2) hemostasis for
(a) mucosal/sub-mucosal defects < 3 cm,
(b) bleeding ulcers,
(c) arteries < 2 mm,
(d) polyps < 1.5 cm in diameter,
(e) diverticula in the colon,
(3) anchoring to affix jejunal feeding tubes to the wall of the small bowel,
(4) as a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

Prescription Use__√__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123601